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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,502	07/03/2003	Richard M. Beane	07917-160001 / UMMC 02-09	4420
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EXAMINER				
BLATT, ERIC D				
ART UNIT		PAPER NUMBER		
3734				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary

Application No.

10/613,502

Applicant(s)

BEANE ET AL.

Examiner

Eric Blatt

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 15-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

DETAILED ACTION

Election/Restrictions

Claims 15-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 11, 2008.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poloyko et al. (US 5,741,276) in view of Poncet et al. (US 5,254,130).

Regarding claims 1, 2, and 6-8 Poloyko discloses a surgical suture placement device (Figures 2 and 3) comprising a handle assembly comprising a plunger 62, an elongated hollow outer tube 36, a suturing assembly having a needle 52 secured to a distal end of the outer tube 36, and a thin flexible actuating rod 64 running between the handle assembly and the needle 52. The suturing assembly also comprises a holding member (track containing needle therein), also considered to be a needle guide having suture aperture 48, that removably holds the needle 52, and a needle cover 38.

Interpreting the handle assembly to further include finger grip members 35, rotating the handle assembly rotates the entire device as a unit about its longitudinal axis.

Thus, Poloyko discloses all elements of claims 1, 2, 6-8, 12, and 13 except for the suturing assembly being rotatably secured to the outer tube and being actuated by the outer tube, inner tube, and rod mechanism as claimed. Poncet discloses a similar minimally invasive device (Figure 1) comprising a functional distal portion 11 that is rotatably secured to an outer tube 7, a flexible hollow inner tube 5 located within the outer tube 7, and a thin flexible rod 15 arranged within the hollow inner tube 5 configured to actuate the functional distal portion 11. This configuration allows the functional distal portion of the device to be separately actuated, rotated, and deflected relative to the longitudinal axis. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Poloyko by providing the suturing assembly such that it is rotatably secured to the outer tube, and providing a hollow inner tube containing the flexible actuating rod such that the suturing assembly may be separately actuated, rotated, and deflected relative to the longitudinal axis of the device as taught by Poncet. So modified, rotating the handle assembly including the plunger 62 and finger grip members 35 rotates the entire device, including the hollow inner tube and the suturing assembly, as a unit.

Regarding claims 3-5, Poloyko does not teach that the needle is hollow and has an open, sharp tipped distal end with rounded edges such that a suture may extend from an aperture on a proximal surface of the needle to an opening at the distal end of the needle. It would have been obvious to one of ordinary skill in the art at the time of

the invention to provide such a needle since such needles were notoriously old and well known to be used for suturing.

Regarding claim 9, Poloyko does not teach that there is a spring that biases the needle plunger into an extended position and the needle into a retracted position. It was well known to provide a spring on such plunger actuating mechanisms in order to bias the plunger into an extended position and the device into a non-actuated position. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Poloyko by providing a spring that biases the needle plunger into an extended position and the needle into a retracted position in order to prevent the needle from projecting from the distal end without the surgeon intending for the needle to do so.

Regarding claims 10 and 11, Poncet teaches that the functional distal end may be angled away from the longitudinal axis of the hollow outer tube. (Figure 1) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Poloyko by having the suture assembly be angled away from the longitudinal axis of the outer tube in order to allow the suture assembly to access a wider variety of anatomies. It would have been obvious to have said angle be a 45 degree angle since the court has held that it is within the knowledge of a person skilled in the art to determine optimal range for the function of a device.

Regarding claim 12, the handle assembly of Poloyko is rotatable. The embodiment shown in Figure 1 of Poncet teaches that the outer tube rotated in order to rotate the functional distal portion. In the embodiment shown in Figure 2, however,

Poncet teaches that the inner tube 19 may be used to control rotation of the functional distal portion, and that said inner tube 19 may extend proximally beyond the outer tube such that the proximal end acts as a handle to allow the user to rotate said "handle", thereby rotating the hollow inner tube and the functional distal portion as a unit.

(Column 6, Line 61 through Column 7, Line 8) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Poloyko by having the handle concurrently rotate the hollow inner tube and suture assembly as a unit since it was a known mechanism by which to control rotation a functional distal portion as taught by Poloyko.

Claims 14 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poloyko et al. (US 5,741,276) in view of Poncet et al. (US 5,254,130) as applied to claim 1 above and further in view of Djurovic (US 6,315,784).

Regarding claims 14 and 25, Poloyko and Poncet teach all elements of claim 14 as previously discussed except for a suture holder attached to the needle guide wherein the needle guide is secured between the needle cover and the suture holder. The suture material of Poloyko is fed from a supply outside the body through the flexible actuating rod and to the suturing assembly. Djurovic teaches that a suture holding spool containing a supply of suture material may be attached at the distal end of a suturing device. (Figure 1) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Poloyko by providing a suture holding spool within the suture assembly since Djurovic teaches that this was a known

alternative for feeding suturing material to the needle. Since the needle cover 38 is the outer housing of the suture assembly and the needle guide is the track containing the needle therein, by positioning the suture holder within the suture assembly as taught by Djurovic, the needle guide would be secured between the suture holder and at least some portion of the needle cover.

So modified, a spool is positioned within element 38, and a suture thread is fed from the spool to the needle 52 located within the curved needle guide. For this configuration to be possible, the suture must pass through a suture hole in the needle cover 38 and into the needle guide to reach the needle 52. As can be seen in Figure 2 of Poloyko, regardless of where the suture hole is located within element 38, it will be adjacent a concave portion of the curved needle guide.

Response to Arguments

Applicant's arguments filed September 18, 2008 have been fully considered but they are not persuasive. Applicant argues that the handle assembly of Poloyko comprises plunger 62, and that rotation of plunger 62 cannot concurrently rotate a hollow inner tube and a suturing assembly as a unit. In response, Examiner notes that the handle assembly may instead be interpreted to include both plunger 62 and finger grip members 35. Rotation of handle assembly 35, 62 will result in rotation of the entirety of the device as a unit about the device's longitudinal axis. The device taught by Poloyko in view of Poncet as discussed in the body of the rejection comprises a handle assembly 35, 62, an outer tube, an inner tube, and a suturing assembly.

Rotating of the handle assembly 35, 62 concurrently rotates the hollow inner tube and the suturing assembly as a unit.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is (571)272-9735. The examiner can normally be reached on Monday-Friday, 9:00 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

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USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric Blatt
571-272-9735

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731